

POST

HOSPITALIZATION

OUTCOMES

STUDIES

Final Report

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POST

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University of Minnesota

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**Post Hospitalization Outcomes Studies
University of Minnesota**

Final Report

The Health Care Financing Administration (HCFA), working in coordination with the Agency for Health Care Policy and Research (AHCPR), contracted with the School of Public Health at the University of Minnesota to conduct the Post Hospitalization Outcomes Studies (PHOS). The contract called for the development of a method for assessing patient outcomes for Medicare beneficiaries following discharge from an acute hospital stay based upon the patients' condition or on the type of medical procedures performed and linking this information to each patient record in the Medicare data base. Information from this research will be used to establish a methodological framework for future outcomes research. In addition, a retrospective by-product of this study may be a model for data collection on both processes and outcomes of care that could be routinely used as part of a quality assurance program that compares the case-mix adjusted outcomes of care among hospitals.

The primary objective of PHOS was to develop an approach to collect information on Medicare enrollees regarding important patient outcomes at relevant time periods after hospital discharge. Patient outcomes of hospital care are influenced by at least four major categories of variables: patient's baseline status before the incident that led to the hospitalization (which determines the likely ceiling on improvement), patient characteristics (both clinical and socio-demographic), specifics of the clinical intervention during the hospitalization, and formal and informal care received after hospital discharge. Information on patient demographic characteristics, outcomes, and care arrangements were collected for this project by telephone interviews with the patient at the time intervals after discharge: within two months (when baseline status was determined retrospectively), between four and six months (to assess intermediate outcomes), and at one year post discharge. Clinical information was abstracted from the patient's hospital medical record and information on service utilization and costs was abstracted from Medicare data files.

The combination of clinical and personal patient characteristics allows for the description of national patterns of outcomes adjusted for case mix.

Data from PHOS provides a more comprehensive picture of long-term outcomes, controlling for hospital care, by monitoring the post-hospitalization course and functional status of Medicare beneficiaries. Understanding the factors that influence patients' outcomes has the potential for improving the quality of patient care by increasing the clinicians' ability to develop appropriate treatment plans for patients with medical conditions. Specifically, the goals of these studies were to:

- determine the types and rates of both positive outcomes and complications or untoward events in the hospital and post hospital periods;
- determine the relationship between particular types of service or combinations of service and good or poor outcomes;
- determine the impact of the hospitalization or specific procedures on the subsequent progression of illness and the changes in health and functional status (how long are achieved benefits maintained);
- investigate the relationship between the patient's satisfaction with the hospitalization and intermediate and long-term outcomes; and
- identify sub-groups of patients or specific patient characteristics that identify those most likely to benefit or have poor outcomes from the hospitalization.

PHOS developed and tested a method for collecting information on outcomes of Medicare patients for selected conditions on an ongoing basis. The research endeavor was divided into a design phase and an implementation phase. Activities in each phase included:

Design Phase

- medical conditions to be studied were selected
- data elements and sources of information were identified
- survey instruments were designed for gathering information on the health status of Medicare beneficiaries prior to and following an acute care hospitalization

- information to be collected from the hospital medical records was identified
- information to be collected from Medicare administrative data was identified
- sampling frame was developed

Implementation Phase

- survey data collection methodology was tested and significantly refined (pretest)
- data was collected from three sources: patients (or proxies), hospital medical records, Medicare data files (including data on Medicare enrollment, service utilization and costs both prior to and after the patient's hospitalization)
- the three sources of data were merged

This merged data base presents a comprehensive picture of the patients' functional and clinical characteristics and patient outcomes post discharge. This report summarizes the activities and results of both the design and implementation phase of PHOS.

DESIGN PHASE

Selection of Medical Conditions or Procedures

The first step in the PHOS design phase consisted of identifying conditions that might be studied. Candidate conditions were chosen based upon the opinion of a Conditions Identification Panel (CIP) composed of four experts (see Appendix A) in the areas of health status measurement, severity measures, geriatrics, and epidemiology of aging.

The CIP members were provided with a structured review of the 25 leading candidate conditions organized according to the following background information (see Appendix B):

- incidence
- consequent costs and speed of accruing sufficient number of cases
- risk of untoward outcomes and associated fiscal consequences
- direct and indirect costs
- intensity and duration of treatment

- amount and extent of post-hospital care
- data on risks, course, and efficacy of interventions

Based upon the above information, the CIP members recommended, in priority order, the following ten conditions for consideration of further study:

- Stroke
- Hip and knee replacement
- Pneumonia
- Cholecystectomy
- some combination, or choice of one, of the following:
 - Chronic angina
 - CABG
 - Congestive heart failure
 - Acute myocardial infarction
- Urinary Tract Infection
- Large and small bowel procedures
- Hip fracture

Following the CIP meeting, the PHOS Advisory Committee (see Appendix C) was briefed on the outcomes of the meeting. The list of ten candidate conditions was then reduced to four for survey development: Total Hip Replacement, Cholecystectomy, Large Bowel Procedures for Cancer, and Pneumonia. HCFA would undertake surveys of two conditions initially and then determine whether to undertake the additional surveys of the two other conditions.

Criteria used in selecting the four conditions for further study included: the degree to which care given during the hospitalization was expected to influence outcomes (positive); to what extent clear treatment choices existed (positive); the prevalence of the condition or procedure (positive); the potential overlap with the topics being studied by the PORTs (negative); and maintaining a balance between medical and surgical conditions.

Stroke was eliminated as a possible condition for study because there was concern that the amount of post hospital care commonly provided following strokes would make it difficult to attribute outcomes to hospital care. This judgment might be different now in light of active interest in the role of thrombolytic therapy. Hip procedures were seen as appropriate for further study but were limited to elective hip replacements. The Advisory Committee felt that hip fractures and hip replacements fall into two different classes because they follow different clinical courses. Elective hip replacements are cleaner cases (have less complications in general) to study and because they are elective, they have greater policy significance. The Advisory Committee also cited interest in studying the different approaches used in elective hip replacement. Cholecystectomy was selected for further study because the procedures used to treat gall bladder problems are going through a major transformation with the introduction of laparoscopic surgery. The timing was appropriate to study the contrast between the different surgical approaches. Pneumonia was considered an appropriate condition for study because it was a medical condition in which the hospital intervention would have a significant effect on outcomes. The various cardiovascular conditions were discarded because of the overlap with work being conducted by the PORTs. Small and large bowel procedures were included for study because of the interest in including a condition that focused on patient satisfaction. Small and large bowel procedures would likely include colostomies for cancer and other conditions. Outcomes might include such things as self-image, social activity, and ability to manage a colostomy.

Identification of Study Conditions, Data Elements, and Sources of Information

In the next step of the design phase of PHOS, Conditions Specification Panels (CSP) (see Appendix D) were convened for each of the conditions to be studied: Elective Total Hip Replacement, Cholecystectomy, Large Bowel Procedures for Cancer, and Pneumonia. In addition, a General Health Outcomes Panel met to address methodological issues around collecting outcomes data. Networking techniques were used to solicit nominees for each panel. Panel members were selected based upon their clinical expertise and availability. Representatives from the pneumonia

and biliary tract PORTs were placed on the relevant CSP. In preparation for the meetings with each CSP, pertinent literature was reviewed and provided to panel members.

During the CSP meetings, each panel was asked to: 1) specify case definition; 2) identify specific outcome measures; 3) discuss what hospital activities influence outcomes; 4) recommend the appropriate intervals and length of PHOS follow-up for patients with that condition; and 5) suggest sources of data, (e.g., patient medical record, hospital operating log, etc.). Based upon the work of the CSP panels, University of Minnesota staff developed survey instruments and chart abstraction guidelines to be used to gather the desired baseline data and data about outcomes for each of the four conditions. Following development of initial drafts of the survey instruments for the four conditions, the CSPs were reconvened to obtain their input on the designing of the instruments and the elements to be extracted from the medical record.

Following the two sets of CSP meetings, the PHOS Advisory Committee and AHCPR staff selected two conditions for pretesting: cholecystectomy and elective total hip replacement. Cholecystectomy was selected because it was a common procedure in which the technology was changing rapidly. Although performed less frequently, elective total hip procedures were selected because there are well-defined interventions clearly related to functional sequelae. While both conditions selected are surgical procedures, they focus on different surgical specialties.

Development of Survey Instruments

The information generated from the CSP members was incorporated directly into the survey instrument development process. For each condition, the survey instruments included questions regarding: condition specific symptoms; general health; functional health; mental health; cognitive ability; living arrangements; and use of post acute care services. Wherever possible existing questions were used in development of the PHOS survey instruments. Specifically, general health, mental health, and physical function questions came from the SF 36, which was used in the Medical Outcomes Study (Stewart et al., 1988). Cognitive questions consisted of the Mini Mental Status Questionnaire (Folstein et al., 1975). Functional status and post acute care questions came

from the survey instruments developed for the Post Acute Care Study (Kane, 1994). Condition specific questions were derived from the experts on the CSPs. Survey instruments for each condition were revised so that each instrument used an identical set of generic questions linked to condition-specific questions (see Appendix E). Although questionnaires were designed for the four conditions initially selected by the Advisory Committee and discussed by the CSPs, only the survey instruments for cholecystectomy and elective total hip replacement went forward to full implementation.

Timing of Survey Instruments

Initially, patients were to be interviewed on two separate occasions; six weeks and six months following discharge. The survey instruments were developed to cover the distinct period before and for six months after discharge. The first questionnaire would provide both baseline health status before hospitalization or surgery and health status at six weeks following discharge from the hospital. The second questionnaire would cover health status at six months following discharge from the hospital. The goal was to gather sufficient information at baseline to separate out the effects of patient characteristics, and post acute care services from the effects of the hospitalization and/or procedure itself on the post hospital outcomes.

During the design phase two factors resulted in a change of the duration of patient follow-up and the frequency of contact following hospital discharge. First, the intake and follow-up survey instruments were tested on several patients (approximately ten patients per condition) to determine the time necessary to complete them. The length of the initially designed questionnaires was over one hour for a functionally able individual. A frail individual would take much longer to complete the questionnaires. The second factor was the recommendation by the clinical panels that follow-up for three of the four conditions take place for one year following discharge instead of six months.

These concerns were presented to the Advisory Committee which made two recommendations to reduce the amount of time that respondents spent on the telephone. They suggested that questionnaires be shortened by eliminating many questions and that the six week survey be divided

into two survey instruments to be administered at two separate time periods instead of one. By dividing the questionnaire, the amount of time the respondent would be on the telephone during the initial interview was shortened. The two week interview was deemed necessary to collect information about patient status prior to hospitalization and symptoms on admission, information that was not expected to be regularly recorded in hospital medical records. Dividing the initial survey had the added benefit of addressing the Advisory Committee's concern about the recommendation of the CSPs for the need for one year of follow-up. The Advisory Committee felt that allowing almost one full year between intake and follow-up without an intervening contact was too long. Thus they proposed adding an additional survey of patients at the mid-point of the year long follow-up. The mid-point survey would include the survey questions from the initial interview that dealt with current status. Because of uncertainty about the appropriate time for the mid-point interview, the sample for each condition was divided into thirds; one third each was interviewed at four, five, and six months following discharge. The four to six month and one year survey instruments were designed to gather outcome data at two points following hospitalization. The three survey points became two weeks, four to six months, and one year post hospitalization.

Despite the inclusion of an extra data point, there was still concern about the length of the questionnaires. To reduce time further, additional questions were deleted and significant skip patterns were developed. The criteria used in deleting questions included the complexity of the questions, the difficulty of asking particular questions over the telephone, and the importance of the information to the overall analysis. For example, questions on the use of specific medications were dropped since it was felt that respondents might not be familiar with medication names or their uses. The cognitive questions were dropped entirely, as they are too difficult to assess. Questions such as "how did you climb stairs" and "did hip pain limit your sexual activity," while important to the clinicians, were determined to be less important or too sensitive for purposes of PHOS. In several cases, similar questions were combined, thus shortening total length while retaining general content. For example, the original draft of the survey instrument included one question about bladder control and one question about use of a catheter. These two questions were

combined in revisions of the survey instrument by rewording the response categories. Appendix F lists the specific questions found in the survey instruments for cholecystectomy and elective total hip replacement (the two final conditions selected for study). The table also outlines the evolution of the survey instruments in light of the considerations mentioned above. Estimated time needed to complete the surveys in their final form was: for cholecystectomy—30 minutes baseline, 35 minutes for each of the two follow-up interviews; for total hip replacement—40 minutes baseline, 45 minutes for each of the two follow-up interviews.

Method of Survey Data Collection

Telephone vs. in-person or mail

The surveys were written for use over the telephone. Cost was the primary reason for choosing telephone interviews over in-person interviews. Mail questionnaires were not considered for this study because the response rate would be lower. The significant number of lost responses could introduce a substantial selection bias into the results. In addition, a written questionnaire would be difficult for frail respondents to complete, thereby increasing the likelihood of refusals or proxies completing the questionnaire. Realizing the inherent problems in selective sample loss with telephone interviews, in-person contacts were to be made with those individuals where refusals were likely (i.e., individuals in institutions who do not have access to a telephone and privacy and patients or proxies who refuse the telephone interview or cannot be reached by telephone).

CATI vs. paper and pencil

The questionnaires as they were developed were suitable for either a traditional telephone survey or a computer assisted telephone interview (CATI) method. The traditional method of interviewers following a paper survey and hand writing responses and comments has both benefits and problems as does the CATI method. The traditional method relies heavily on interviewer training in order to implement skip patterns in the survey. If the survey skip patterns are complicated, the interviewer could have difficulty in maintaining the flow of the interview as well as in obtaining accurate information. The CATI program is specifically designed to help

interviewers in navigating skip patterns. The skip patterns developed in the PHOS survey instruments were specifically designed so that they were easily navigated by either survey method. CATI provides immediate data entry. The CATI also verifies responses as they are being entered, to insure that they fall within permissible ranges. However, the CATI cannot verify if the response is correct. Interviewers are trained in how to conduct the interview, focusing on the flow of the conversation, how to deal with difficult situations in which the individual does not want to respond or is having difficulty responding, etc. The CATI can interrupt the conversational flow developed by interviewers probing for more information by moving too quickly. The manual telephone interview method was used due to the increased expense and development time required by the CATI method.

Medical Record Data

In addition to the information obtained directly from patients through the questionnaires, information was collected from hospital medical records and Medicare utilization data files. Hospital medical records were abstracted to obtain information on severity of the condition and use of hospital services. Specific information collected included: 1) preoperative factors including sociodemographic characteristics, comorbidity, risk factors, and mental health; 2) intra-operative factors such as type of procedure; and 3) postoperative factors including care given during the hospital stay, adverse events occurring during the hospital stay, and discharge status and destination. This study did not include information from physician medical records, placing a heavy reliance regarding health status prior to admission on information gathered from the patient, and from hospital admission notes and utilization of services prior to hospitalization (Medicare data).

The CSP members developed lists of information that should be collected from the hospital medical record. These lists were very inclusive (see Appendix G). A central issue in collecting data from the medical record was identifying the best approach to be used for the chart abstraction. The first option was to develop a method specifically for use by PHOS which would permit collection of any and all relevant information (given that it can be found in the medical record). The specific

methodology would not, however, be readily accessible to other research efforts in the future. A second option was initially explored; to use the relatively new UCDS chart abstraction methodology in use by some PROs. The advantage of using UCDS was that the method used in PHOS would possibly be a dominant method of chart abstracting in the future. A discussion was held with staff from the Health Services Quality Bureau, who indicated their willingness to make modifications in the UCDS for use in this study, expanding it to include additional items needed by PHOS. While in the process of making those modifications, the intention by the federal government to support the UCDS system changed. Realizing the UCDS would not be the dominant system used in the future, it was decided to develop a unique abstraction tool that included all of the items originally deemed important by the CSPs.

Medicare Data

In addition to information collected from surveys and medical records, Medicare data can provide information on utilization and cost of care. It can also provide information on sociodemographic characteristics; comorbidity deduced from prior utilization and recorded diagnoses; post discharge complications can be calculated. Medicare administrative data includes a description of services utilized and costs incurred by each type of service, inpatient, physician, outpatient, home health care, hospice, and durable medical equipment. The theory underlying this project was that the Medicare administrative data could be very useful in tracking patient outcomes if it were coupled with clinical information that delineated risk factors. For example, a question of great salience is whether patients undergoing elective hip procedures get longer life from different types of prostheses. By identifying the type of procedure performed and the type of prosthesis used (and being able to adjust for patient characteristics) it is possible to track in the Medicare data base to compare the rates for reoperations on the same hip in subsequent years. Likewise, the Medicare data base can be used to track the relative effectiveness of laparoscopic and open cholecystectomies by looking for evidence of subsequent gall bladder problems or sequelae of the surgery.

Sampling Frame and Methodology—Initial Plan

Selecting Hospitals/Communities

The overall goals of the sampling design were to: 1) identify a nationally representative sample, 2) insure an adequate sample size to determine predictors of outcomes, 3) enable the identification of the sample within a six month time frame, and 4) include a sample of urban and rural hospitals for cholecystectomies. During the design phase of the project a sampling plan was developed with the goal of using a selected number of hospitals to identify a nationally representative sample of patients from a limited number of geographic locations. In order to achieve a nationally representative sample a two stage clustering technique was suggested. The first cluster being Metropolitan Statistical Areas (MSAs) and the second cluster being hospitals within MSAs. The original proposal suggested selecting ten MSAs geographically disbursed across the country. The number of hospitals to be recruited in each location was calculated based upon the total number of cases to be collected during the six month data collection period (an estimated ten hospitals per location or MSA to yield the intended sample size of 1100 cases per condition).

Upon further review of the historical number of discharges by hospital for cholecystectomy and elective total hip replacement it was determined that it would be difficult to obtain the intended sample size within the allotted six month time frame by utilizing ten hospitals in each of ten MSAs. Most MSAs did not have ten hospitals discharging enough patients in either of the two conditions being studied to generate the necessary sample size. The plan was modified to include more MSAs so that those hospitals conducting a relatively large number of procedures would be included while eliminating the facilities in each MSA with very low numbers of procedures. The total number of participating hospitals and the number of cases needed remain unchanged. Six MSAs were to be selected from each of four census regions for a total of 24 MSAs. Within each MSA approximately four to six hospitals would be recruited from which to collect the intended patient sample, for a total of approximately 100 hospitals. Based upon prior experience, it was estimated that contacts would need to be made with 120–150 hospitals in order to reach the goal of 100 hospitals. To

control for hospitals that did an unusually large number of procedures the number of patients coming from any single hospital was capped at 30 cases per condition.

The sample was also expanded to include rural hospitals. In addition to the 1100 cholecystectomy cases sampled from hospitals within MSAs, a sample of 400 individuals discharged from rural hospitals for cholecystectomies was added. The sample was expanded to include rural hospitals for several reasons. Inclusion of a sample of rural hospitals was specifically requested by AHCPR staff because rural hospitals represent a different mode of practice. It was important in the study of cholecystectomy that the respective outcomes of laparoscopic surgery be compared to traditional cholecystectomies. The diffusion of the technology is often variable (urban fast/rural slow) therefore it was anticipated that most urban hospitals would be performing laparoscopic surgery when the data collection phase of the study occurred. It was likely that the new procedure would not be in use as much or as rapidly in rural hospitals. By including rural hospitals in the sample the differences between urban and rural hospitals in introducing new technologies successfully could possibly be measured. Based upon the average number of cases per rural hospital per month (i.e. ten cases per month over six months, or less than two cases per month) it was estimated that 40 rural hospitals would be needed. Approximately two hospitals located just outside each MSA (within 100 miles of the MSA) would be identified for use in the primary study.

Once recruited, hospitals would identify eligible patients by condition. Specifically, hospital staff were to monitor daily the admissions of Medicare beneficiaries 65 and older for appropriate admitting diagnoses and discharges to the hospital which fell within specific ICD procedure codes. Names and addresses, etc. of all patients selected were to be forwarded to the University of Minnesota data collection center immediately upon discharge.

IMPLEMENTATION PHASE

Pretest

Following creation of the survey instruments and sampling frame, a pretest was conducted. The purpose of the pretest was to test of the logistics of patient identification and the administration of survey instruments, as well as data collection, editing, and coding procedures. All sampling and survey procedures described earlier were tested and survey item quality and response rates were assessed. Ease of administering the questionnaires, clarity of questions, and specific terminology was checked. Items that were problematic in the survey instruments were identified. The length of the questionnaires was reviewed based upon the ability of patients to complete the survey, specifically looking at whether or not patients recovering from surgery are able to talk on the telephone for 30 to 45 minutes. The accuracy of the Medicare Identification Number obtained from hospitals was verified by calling up the records for the sample to see if there was a Medicare hospitalization for the corresponding date. The reliability of information given by proxies was assessed by comparing responses from a sample of patients to those obtained from the designated proxy for those individuals. As a result of the pretest, specific guidelines for interviewers were developed regarding how to determine when contact with a proxy is necessary because a patient is too mentally confused or cognitively impaired to be a reliable respondent. Procedures to identify and track patients following hospital discharge and between interviews were refined, and the ability to obtain information from rural hospitals and patients was verified. In the interest of time, only the baseline and midpoint interviews were conducted and the midpoint interview was conducted at three months following discharge.

A major issue in the sampling methodology was the ability to recruit the required number of hospitals both in urban and rural locations. During the pretest, Milwaukee, Wisconsin, and Little Rock, Arkansas, were selected as sample MSAs because of their geographical location and other assumed characteristics based upon previous work in those areas. In general, the south is traditionally a difficult area to recruit hospitals as compared to the upper midwest. Familiarity with the University and relatively close proximity to test in-person interviews were also factors.

The pretest began by using a subset of the original design; hospitals were recruited in the two MSAs and the surrounding rural areas. Support for the project was solicited from the state medical associations and the hospital trade associations. Direct appeals to the hospitals were made through letters and telephone calls. Of 63 potential hospitals, 27 hospitals (43%) were successfully recruited. It was especially difficult to recruit rural hospitals (of the 37 potential hospitals in the two rural areas 11 (30%) were successfully recruited. Reasons given for not participating included lack of time, lack of available staff, too much research activity already, no interest, lack of trust of the government and academia. Appendix H gives more detailed information about characteristics of the participating and non-participating hospitals in those two states.

Patients were selected by condition from the participating hospitals. Specifically, hospital staff were asked to monitor daily the admissions of Medicare beneficiaries 65 and older for appropriate admitting diagnoses and discharges to the hospital which fell within specific ICD procedure codes. Names, addresses, etc. of all patients identified were forwarded to the University of Minnesota data collection center immediately upon discharge. Typical hospital personnel involved in identifying patients included medical records staff, nursing supervisors, and admission personnel.

In addition to difficulties in recruiting hospitals, it was apparent early in the project that the participating hospitals were under reporting cases. The reason for under reporting of cases was unknown, although it was thought to reflect lack of staff and lack of interest among the medical records personnel assigned to the project. To determine the extent of under reporting during the study period, cases of hip replacements and cholecystectomies for the participating providers were obtained from the National Claims History (NCH) file. The NCH file includes utilization records that are available through the Medicare data system shortly after the bills are paid by Medicare. Appendix I compares the patients identified by hospitals with the patient claims submitted to HCFA and found in the NCH file.

Sampling Frame and Methodology—Revised

As a result of problems recruiting hospitals and identifying patients through hospitals, a new method of patient identification was developed during the pretest. This method used the Medicare fiscal intermediaries (FI) to identify patients who had undergone one of the two procedures at the time the bill was originally submitted by the hospital to the FI. Using FIs to identify cases was tested in Wisconsin, Arkansas, North Carolina, Nevada, and Illinois.

Information needed to allow patient identification and medical record abstraction was collected directly from the patient's initial bill received from the FIs. Information found on the patient bill included: full name, address, procedure codes, diagnosis codes, Medicare status and identification number, sex, date of birth, date of admission, date of discharge, insurance status, medical record number, and hospital provider number (sample form included in Appendix J). National CD ROM telephone directories and directory assistance were utilized to obtain the patient's telephone number.

This method was found to be much more reliable and efficient: 1) fiscal intermediaries were recruited more easily than hospitals; 2) the quality of the data, especially the Medicare patient identification number (HIC number), was better when reported by the intermediaries; 3) the volume of cases generated by FIs was greater; and 4) the printing of paper copies of bills and sending the information to the University of Minnesota required a minimal amount of effort on the part of FIs. Appendix K compares the accuracy of HICs submitted by the hospitals and the FIs with the information provided in the HCFA Enrollment Database. No other outcomes research project has used this method of patient identification. Appendix L indicates the number of hospitals represented in the pretest when identifying patients by FI claim and their characteristics.

Sampling based upon claims data from FIs raised the issue of timeliness. Originally, baseline data was to be collected within two weeks of discharge. The baseline interview was specifically designed to gather information on the respondent's status prior to hospitalization for comparison to later post-hospitalization status. Therefore, it needed to be completed as early as possible following discharge to accurately capture information about pre-hospitalization status. During the pretest, the

mean length of time between date of discharge and the date information was received at the University of Minnesota was 38 days and close to 85 percent of the FI sample was received within 60 days from discharge (Appendix M).

Because the baseline interviews includes questions about pre-hospitalization status, it was important to test how recall was altered by a delay in identifying patients following discharge. This comparison was important because using the FIs meant some delay in identifying patients if hospitals did not submit bills promptly. Hence, some interviews were done later than the originally planned two-week window. To determine the extent of recall differences, during the pretest a subset of respondents (approximately 20 per condition) were administered the baseline survey as the initial interview as well as three months following discharge. Appendix N displays the comparisons of the responses at two weeks after discharge and at three months following discharge. The information is arranged to show the average size of the differences between the responses at the two time periods as a function of the size of the range of possible responses. In general, the differences represent a very small fraction of the scale range (on the order of 5-10 percent), suggesting that the two approaches produced comparable results.

Patient Selection

The respondent universe included all elderly non-HMO enrolled Medicare beneficiaries, age 65 and over, discharged following one of two procedures; cholecystectomy and elective total hip replacement from hospitals served by selected FIs. Printed copies of claims were sent from the FI to the University of Minnesota approximately twice a week via overnight mail. Staff at the University of Minnesota screened each claim for a valid Medicare claim number (HIC), age of patient, admitting diagnosis, HMO status, and length of time from hospital discharge to receipt at University of Minnesota. Individual patient HICs, first name, last name, and date of birth provided by the FIs were validated against HCFA's Medicare Enrollment Database (EDB). The EDB is a file which contains identifying information on all currently enrolled beneficiaries.

HMO members were omitted from the sample because data on the hospitalization of HMO members received by HCFA are incomplete. Obtaining comparable data from the managed care plans would be costly, difficult to obtain, and in some cases, not available since they are not required to report cost data. It is estimated that at the time this study began only 7 percent of Medicare beneficiaries are enrolled in HMOs (of which 5 percent were in risk-based HMOs). Therefore it is difficult to capture enough HMO enrollees from a generalized nationally representative sample. HMO enrollment is not evenly distributed across the country. For example, Medicare HMOs are very active in southern California and Minnesota but much less so in New England and the South. Medicare HMO enrollees are also more prevalent in urban areas and rare in rural communities. With such an uneven distribution of enrollees, it would be very difficult to capture enough HMO cases from every area that had possible access to an HMO to treat HMO membership as a full explanatory variable in the analysis. Oversampling from areas where there is high market penetration among Medicare beneficiaries would yield a sufficient sample but would lose generalizability. The sample would be useful to contrast HMO and non-HMO patients, but would require additional corrections for city effects (e.g., the availability of nursing home beds or the ratio of surgeons to population or style of practice or the very fact that a lot of the Medicare population is enrolled in HMOs). If a sample population could be identified, only survey and medical record data would be available without links to utilization or cost data. Critics could assert that omitting HMO members slightly limits generalizability of the PHOS to all Medicare beneficiaries. However, in a study of the outcomes attributable to the post-hospital care received by a sample of Medicare patients, the University of Minnesota Post Acute Care Study found that membership in an HMO had no consistent effect on either type of post-hospital care received or the outcomes of that care (Kane, 1994).

The specific ICD procedure codes used for the two conditions were as follows:

Cholecystectomy:	51.22 total cholecystectomy and 51.23 laparoscopic cholecystectomy
Elective Total Hip Replacement:	81.51 total hip replacement

The study of cholecystectomy was limited to cholecystectomies performed as the primary procedure. Patients who had a secondary or incidental cholecystectomy were removed from the study. The study of elective total hip replacements was limited to only those individuals with diagnoses of osteoarthritis. As a result patients with hip fractures (ICD-9-CM codes 835.0–835.13 and 820.0–820.9), rheumatoid or other inflammatory arthritis (714.0), traumatic arthritis (716.10–716.19), congenital hip dysplasia (754.30, 755.63), Legg-Calve-Perthes disease (732.1), or Paget's Disease (731.0) were excluded from the sample. Revisions of prior hip replacement procedures (81.53) or bilateral operations where the first hip was operated on within one month were also excluded. The intent in defining the samples in this manner was to collect a clinically homogeneous sample that can be readily understood for purposes of generalizability. Five percent of cholecystectomies and three percent of total hip replacements were removed from the pretest sample for these reason.

The focus of this study was on patients who were discharged alive. However, to get a full description of outcomes, hospital charts were abstracted on any Medicare patient who died while in the hospital or prior to our contacting them within two months following discharge. During the pretest less than 2 percent of cases died before the initial interview.

Pretest Results

During the pretest claims data for 1671 patients were received by the University of Minnesota. Of that number just over half (54%) were determined to be eligible for the study. Screening the claims for accuracy up front is essential based upon this method of identification. Patients were excluded based upon our selection criteria, age, and being received outside of the intended interview window. Of the eligible sample, 96 percent of the patients were successfully located (Appendix O). From those 863 patients located, survey interviewers attempted to complete the baseline and follow-up interviews on a smaller subset, 359 individuals (195 cholecystectomy patients and 164 elective total hip replacement). Of those 359 potential respondents, 96 percent completed the baseline survey, four percent refused to participate. Another six percent of the

sample did not complete the follow-up interview either because they refused, were deceased or their location had changed. The overall response rate was 90 percent (Appendix P).

Two central issues addressed in the pretest were the ability to locate patients based upon claims data (which did not include telephone numbers) and the ability to track patients over time. From the total FI eligible sample of 895 for both conditions, 863 patients or proxies (96 percent) were located, (Appendix O). Of the cases for whom a telephone number was obtained, 68 percent of the sample was located by using telephone directory assistance, 31 percent by hospital inquiries, and 1 percent by other sources such as relatives. Once located, less than 7% of the sample was lost to follow-up within the three month time frame used in the pretest. Of that number, 2% were due to death. Expectations for the full study were set based upon this information (Appendix P).

During the pretest the accuracy and reliability of proxy responses was tested against patient interviews. Both patients and proxies were contacted at baseline. Responses were compared. The level of agreement was from 30 percent to 100 percent and virtually all were significant (Appendix Q). Based upon these results the use of in-person interviews was eliminated. The decision was made to use proxies where the individual was unavailable or unable to answer the survey questions. Specific criteria were established to assist interviewers decide the need for a proxy. The goal was to avoid proxy interviews whenever possible. During the pretest 89 percent of the surveys were completed by telephone, 2 percent by in-person interviewers, and 9 percent by proxy (Appendix R).

FULL IMPLEMENTATION

Sampling Frame and Methodology

The full study began in September of 1994. Given the success during the pretest in using fiscal intermediaries, the full study employed the same method to identify patients. Cases were identified through 12 fiscal intermediaries (FIs) (Appendix S) who historically processed the greatest number of bills for cholecystectomy and hip replacement (originally thirteen FIs were

selected but one declined to participate due to resource limitations). The rationale for this sample was to obtain a nationally representative sample that would also generate enough cases. These FIs covered many states, but we restricted the data used for this study to those states where the FI serviced over half the Medicare population. These states are shown in Appendix S. In one case an FI covered more than half of three states and we elected to draw patients from only one of these, Mississippi. The FIs began sending claims data in late October 1994. Sample intake took approximately eight months to complete.

To determine predictors of outcomes an adequate sample size was needed. For each condition PHOS sampled over 1,100 patients from urban/suburban locations throughout the 12 states served by the participating FIs. An additional sample of over 400 patients from rural hospitals was used for cholecystectomy.

Claims were screened by staff at the University of Minnesota based upon established eligibility criteria including age, secondary procedures and primary diagnoses, length of time between discharge and receipt in Minnesota, and bad information such as incorrect HIC number. All potential cases were matched against the HCFA Enrollment Database to verify the HIC number. Once the case was included in the study sample, interviewers attempted to locate a correct telephone number and contact the individual. Respondents were surveyed within two months of discharge from the hospital, at 4 to 6 months following discharge, and at one year following discharge.

The exact number of subjects to include from each FI was determined based upon historical data regarding the annual number of patients with each diagnosis discharged from hospitals in states served by each FI. The number of patients to be discharged in the ten month period of data collection was estimated and the correct sampling fraction within each FI was developed so as to sample proportional to size and to keep the data collection period the same for all FIs.

Next the cases were stratified by whether the hospital was in an urban or rural area (rural defined by the definition used in the HCFA Provider of Services file.) This allowed for a sufficient

sample of cholecystectomy cases obtained from rural hospitals. The proportion of proprietary, non-profit, local government-owned, teaching, small and large hospitals included in the sample was expected to be nationally representative across the sampled FIs. Therefore it was not necessary to sample separately from stratified groups representing these characteristics in order to say something about different types of hospitals in the analysis. Appendix T discusses the design effect related to the sampling plan.

The sampling design for the full study originally focused on inpatient hospitalizations and used ICD procedure codes for identification. Upon further examination of the discharge rates for the two conditions being studied it was determined that a significant number of laparoscopic cholecystectomies were being performed on an outpatient or same day surgery basis. The sampling method was modified in order to capture a sufficient number of inpatient open cholecystectomies, inpatient laparoscopic cholecystectomies, and outpatient laparoscopic cholecystectomies, specifically 500 cases each. The number of cases needed from each FI was then distributed proportional to the historical number of discharges by each category. The number of inpatient open cholecystectomies, inpatient laparoscopic cholecystectomies, and outpatient laparoscopic cholecystectomies was set to be equal (500 cases each) instead of proportional to historical numbers for two reasons: first it was believed that the historical information did not adequately reflect the changing nature of cholecystectomy surgery and therefore did not adequately reflect current and future numbers of procedures performed and second this method would generate enough cases in each group to make subgroup comparisons (Appendix U).

In order to accomplish this change the FIs were first instructed to include outpatient claims in the data being sent to the University of Minnesota. Second, the tracking system at the University of Minnesota used to screen eligible claims was modified to include type of bill (bill type code structure in Appendix V) and HCPC codes used for paying outpatient claims. The eligible HCPC codes included: 47600–47620 for open cholecystectomy and 56340–56342 for laparoscopic cholecystectomy.

During the full implementation, University of Minnesota surveyors attempted to locate and contact the patient within ten days of receiving information from the FI. Claims falling outside of the two months post-discharge window were omitted from the sample. During the full implementation close to 90 percent of the FI sample was received at the University of Minnesota within 60 days from discharge and approximately one-half was received within 30 days (Appendix W). A total of 526 cases, 7.7% of the total intake sample, were excluded from the sample because of being outside the two month window.

Medical Record Abstraction

With the endorsement of HSQB, Peer Review Organizations (PRO) in each of the states/areas served by the participating FIs were contacted to participate in the study. Conducted as a cooperative project under the PRO contract with the Health Care Financing Administration and as part of their regular PRO review activities, PROs were asked to obtain copies of the medical records for all patients who completed the baseline interview (or proxies completed the interview) or who were deceased prior to baseline. Medical records were forwarded on to a central location (the Colorado Foundation for Medical Care) for abstraction. Hospital records were abstracted using a tool especially designed for this project using guidelines established during the design phase of the project by the clinical experts (the complete abstraction tool is located in the Data Collection Manual). The instrument and training for abstractors was tested. Revisions were made until reliability for each individual item was 90 percent or greater. Reliability of the instrument and abstractors was checked periodically during the review process.

Results

Sampling Frame

Appendix X indicates the number of completed surveys at each data point. The initial eligible sample included 2701 cholecystectomies and 1640 total hip replacements. The final sample used to gather other sources of data including hospital medical record and Medicare data was based upon

those individual completing the baseline interview and those individuals deceased at baseline, 1569 cholecystectomies and 1133 total hip replacements.

A ten percent loss in the sample over the course of the project was anticipated. In fact, the hip replacement sample declined 6% and the cholecystectomy sample declined 9.8% from baseline to one year. Of those 1,423 patients (947 cholecystectomy patients and the 476 total hip) who did not complete any of the three survey interviews 62 patients (49 cholecystectomy and 13 hip) died prior to baseline, 26 patients (17 cholecystectomy and 9 hip) died prior to the midpoint, and 40 patients (27 cholecystectomy and 13 hip) died prior to the one year follow-up. According to medical records information, four hip patients and eleven cholecystectomy patients died in the hospital. In addition, respondents were labeled incomplete if the survey interviewers were unable to locate a valid telephone number, the interviewers were able to locate the individual but were unable to complete the interview within the specified time window, the individual refused, or there was no proxy available. Appendix X also indicates the proportion of cases failing to complete the surveys at the three data points for the above reasons. Although not specifically tracked during the course of the project, the loss of sample by FI was fairly consistent across the FIs, as indicated in Appendix Y.

To test the adequacy of the data collection procedures separate analyses were performed on each sample. All analyses were performed by using a logit specification and regressing personal characteristics (gender, length of stay and age—all information obtained from the FI claims data) along with dummy codes for each of the fiscal intermediaries from whom the data was collected. Gender was coded 1 for female, 0 for male. Length of stays was coded in days, and age was coded in years. First an analysis was conducted showing the differences between those subjects that were deemed eligible and were received in a timely manner and who completed the initial baseline interview and those subjects that were deemed eligible and were received in a timely manner but a baseline survey was not completed. Both the cholecystectomy and total hip equations were significant as shown in Appendix Z (cholecystectomy: Model $X_2=184.720$, $df=15$, $p<.000$;

Total Hip Replacement: Model $X_2=81.658$, $df=14$, $p<.000$). For both samples, females, those patients with longer lengths of stay, and older subjects were less likely to complete the survey. Additionally, for the cholecystectomy sample, those who had a laparoscopic surgery were more likely to complete the survey than those receiving a traditional surgery. There was significant variation among the FIs but it was less pronounced than in the other samples studied. On the other hand, there is no reason to suspect that the FI variable would be significant in this equation.

Using claims data supplied by FIs was a fully efficient method of identifying patients. A thorough screening of claims, however, was necessary to identify incorrect information. Appendix AA shows the number of people excluded from the sample for various reasons: 36.5% of the cases had a bad HIC number or other bad data; 18.4% were too young; and 38.2% of cases were excluded because they did not meet the procedure and diagnosis rules. Overall, 36.3% of cases received in Minnesota were excluded from the study, leaving the remaining eligible sample of 2,701 for cholecystectomy and 1,640 for hip replacement.

A distinction should be made between exclusion from the sample on the basis of not meeting the study criteria (i.e., ineligibility) and loss from the study because of notification after the target time window. Those in the latter case met the study criteria and hence are part of the basic sample, but they were not included because the notification of their hospitalization arrived after the time window for the baseline interview. These cases pose a potential bias to the sample to the extent that the characteristics that made their notification late also distinguished them from those with more timely notification.

Beneficiaries who were forwarded to the University of Minnesota and met all the eligibility criteria were compared to those that were determined to be ineligible using a logit specification model. Both the cholecystectomy and the total hip replacement equations were significant (Cholecystectomy: Model $X_2=806.610$, $df=15$, $p<.000$; Total Hip Replacement: Model $X_2=151.836$, $df=14$, $p<.000$). The results of this analysis are shown in Appendix AB in columns 1 and 3 of the table for cholecystectomy and hip replacement respectively. Examination of these

columns shows that those who were ineligible had significantly shorter lengths of stay, were older than the eligible sample and, for the cholecystectomy sample, were more likely to have had a laparoscopic surgery. In addition, there was significant variation between FIs in the number of ineligible sample they forwarded.

A second analysis looked at eligible sample members who arrived in Minnesota too late to be interviewed (columns 2 and 4 in Appendix AB). Again, using a logit specification model with the dependent variable coded 0 for eligible subjects and 1 for ineligible subjects, both the cholecystectomy and total hip replacement equations were significant (Cholecystectomy: Model $X^2=209.062$, $df=14$, $p<.000$; Total Hip Replacement: Model $X^2=71.821$, $df=14$, $p<.000$). While the overall results of both the cholecystectomy and total hip replacement samples were significant, there are no variables of interest that are significant. There was significant variation between FIs in their ability to identify and forward sample patients in a timely manner.

Of those patients determined to be eligible for the study, 456 or 10.5 percent were never found. The information provided by the FI was incorrect or insufficient to locate the individual. The individuals that were located were primarily found using a CD ROM phone disk directory. The second most often used source of information was directory assistance (Appendix AC). In some cases neighbors provided forwarding addresses or special efforts had to be made to track down the respondents.

The use of proxies in the full study was somewhat similar to the experience in the pretest. In 11 percent of the cholecystectomy cases a proxy was used while 6 percent were used in total hip replacement cases (Appendix AD). The lower use of proxies for hip replacement cases reflects the better health status of patients undergoing this elective procedure.

The resulting sample yielded about two cases per condition per hospital instead of the ten originally planned, but the goal was not to examine cases in specific hospitals. Appendix AE indicates the number of hospitals per FI. Appendix AF indicates the average number of cases and

range per hospital per FI. Finally, Appendix AG shows the number of hospitals participating from each FI by various hospital characteristics.

Medical Record Data

Hospital medical record data was requested for all patients who completed the baseline interview or were deceased at baseline. Of the 2702 records requested, 2666 were received and 2602 were abstracted, 98.7 percent. Once a record was received for abstraction it was screened again to see if the patient met the eligibility criteria. In addition to reliability testing that was completed during development of the instrument, ten percent of all of the records abstracted were abstracted by a second reviewer. Overall reliability was within 3.65 percent for total hip replacement and under 2 percent for cholecystectomy.

Medicare Data

As with medical record data, Medicare utilization files were requested for all respondents completing the baseline survey and for those patients who were deceased at baseline. The request included the following files: Denominator (which indicates if the individual is a member of an HMO), MEDPAR (for inpatient utilization data) Hospice, Outpatient, HHA (Home Health Agencies), DME (Durable Medical Equipment), and Physician Part B (which also includes clinical lab data). Data was obtained for the period one year prior to through one year following the date of discharge for the two procedures being studied. Not all patients have data for a full year following the discharge date due to the fact that requests for Medicare data take some time to process. The request was submitted so as to include as many patient records as possible and still receive the information before the end of the project.

Records for all but 25 hip patients and 14 cholecystectomy patients were located in the files sent from HCFA. Even though the HIC numbers were checked for accuracy against the Medicare Enrollment Database before patients were entered into the study, in some cases it was difficult to identify the correct HIC number prior to the request for data being submitted to HCFA. PHOS files were revised based upon information obtained while locating the medical record and rechecked

against the Enrollment Database. A resubmission requesting data on these 39 patients with revised HIC numbers may be successful.

Inpatient and outpatient files were checked to find the sentinel event that caused the individual to be entered into the PHOS study. The sentinel event was found in the MEDPAR file for all 1106 hip patients, for which there were records. The sentinel event was found in MEDPAR for 968 cholecystectomy patients and 938 patients in the Outpatient file. Forty-nine patients had only Physician Part B records. In addition, 154 patients having MEDPAR or Outpatient records had no Physician Part B records. Patients are expected to have both a facility (inpatient or outpatient charge) as well as a physician (surgeon) charge for the sentinel event. Absence of one or the other may be due to the provider billing late or the claim being denied and resubmitted due to a variety of potential problems. Appendix AH indicates that those cholecystectomy patients with inconsistent data are not significantly different from the rest of the sample.

All patients were checked against the denominator file to determine HMO status. Seventy-five cholecystectomy patients were in HMOs at some time during the study period and 61 total hip replacement patients were in HMOs at some time during the same period. There is the potential for limited or incomplete utilization data on these individuals.

Linking Data

Linking and verifying critical information across data sources was made difficult by inconsistent and questionable or absent data. For example, 64 cases that met the eligibility requirements based upon claims data later were determined ineligible based upon medical record data. This data quality concern was most evident in how inpatient and outpatient status was determined. Type of bill indicated on the claim form was used to mark a claim as outpatient for sampling purposes. There were inconsistencies found between type of bill and ICD 9 procedure code and HCPC code (open cholecystectomy listed as an outpatient claim). The same problem arose when comparing bill type with length of stay (Appendix AI). There is some evidence of errors contained in the FI data as shown by examining the length of stay by bill type. Ninety

eligible cases who were presumably treated as outpatients have length of stay of two or more days. To further understand what occurred, additional information was abstracted for all laparoscopic patients to determine from hospital records the outpatient, inpatient status. Abstractors first concluded whether the patient was originally a hospital inpatient admission based upon physician documentation and the hospital face sheet. If the patient was admitted to an outpatient unit such as observation, short procedure or stay, day or ambulatory surgery, the abstractors looked at where the patient went directly after the post anesthesia care unit/recovery room (hospital bed, observation, or discharge) and if the documentation indicated the outpatient status converted to inpatient status based upon physician orders. Appendix AJ gives the additional information by length of stay. This information suggested that while some of the claims data may be erroneous, the definition of outpatient status may also not be clear. There appear to be some cases that are true outpatient cases while others are only probable or dubious at best. Appendix AK compares the definition of outpatient status by the various data sources. While there is considerable agreement, there are still some questionable cases.

Analysis of Results

Appendices AL, AM, and AN offer a preliminary glance at the data from the elective hip replacement cases. These are still uncorrected for missing data, although the number of missing responses for any single question is usually quite low ($<0.05\%$). No corrections for other factors have been done, nor have any scales been developed. The sample consisted primarily of individuals between 65 and 79 years of age. They were predominantly white. A little over half were still married. Over 60 percent of the hip patients were female (Appendix AL). The length of stay in the hospital for this procedure ranged from less than one day (again pointing out potential errors in the FI data) to over 40 days and averaged just over six days (Appendix AM).

There was substantial improvement in walking distance, with fewer people using an assistive device. Various types of movements were easier. More people left the house. The only area that appears counter-intuitive was the increased use of an assistive device for socks and shoes. There

was a general reduction in pain of different types. Hip pain was expected to be different after surgery with less specific hip pain and more thigh pain (Appendix AN).

Appendices AO, AP, and AQ describe the initial results for cholecystectomies. The sample population tended to be slightly younger, the majority being between 65 and 74. They were predominantly white and slightly more, 62.2%, were still married. Again, over 60 percent of the sample were female (Appendix AO). The length of stay in the hospital, as anticipated, varied greatly between open cholecystectomies and laparoscopic cholecystectomies; laparoscopic cholecystectomies were predominantly grouped between less than one and two days (30% were done as outpatients) while the open cholecystectomies ranged between less than one day to over 40 days with the median length of stay just over seven days (Appendix AP).

The proportion of patients who reported a pain similar to classic cholecystitis pain dropped dramatically but the reports of individual types of pain varied. Symptoms like nausea, vomiting, and belching improved but flatulence did not. Response to greasy and fatty foods and dairy foods was less severe but other foods still brought on pain at least as often. About three-quarters of the patients had resumed their usual activities by the time of the first follow-up survey (the baseline survey completed within two months of discharge). There was some improvement in overall ratings of health (Appendix AQ).

Lessons Learned

The goal of PHOS was to develop an approach to collect information on Medicare enrollees regarding important patient outcomes at relevant time periods after hospital discharge and to link this outcomes data with Medicare utilization data. The methodology used to identify patients for inclusion in the study and to obtain different sources of data was efficient and at relatively low cost. The quality and accuracy of the initial claims data may be suspect however which caused difficulty in linking data sources and leads to further research questions.

Specifically, the method of using fiscal intermediaries to identify patients was an efficient method to identify a large national sample within a relatively short time frame and with minimal

cost. The original study design included utilizing 13 FIs to identify patients. All but one of those FIs agreed to participate. Recruitment was fairly easy, with relatively minor expenses incurred by each FI. With one less FI than originally anticipated, sample intake was still completed within the allotted time frame, allowing for a change in eligibility criteria midway through intake (addition of using HCPC and Type of Bill to insure an adequate number of outpatient laparoscopic procedures).

There is a potential concern regarding sample bias. It is difficult to say the sampling method yielded a truly nationally representative sample because it is impossible to weight the sample back to some identifiable base. Sampling by FI does not equate to a proportion of Medicare patients by state because FIs serve only part of states or overlap into other states and into states served by other FIs. Another concern is the completeness of the sample drawn by the FIs. There is no means to test if the patients identified by the FIs are all of the possible patients. Based upon the procedures set in place and discussions with staff at the various FIs, the sample should be pretty complete in that all potential cases were forwarded to the University of Minnesota for potential inclusion in the study. The remaining concerns then are the cases that simply were not submitted for payment by providers in a timely manner to be included in the study. There is no way to determine the extent of these cases.

While the cost to identify patients was fairly low, there was a higher cost to screen the claims. Over 36% of the cases forwarded to the University of Minnesota were determined to be ineligible for the study. In addition, another 8% were lost from the sample due to the late submission of the claim. Although the individuals met all eligibility criteria, their claims were received after the established interview window had passed.

Before we attempt to attach any meaning to these results, we must remind ourselves of the limitations of these analyses. First, the sample size for the eligibility analyses are large and we should depend upon the size of the significant odds ratios rather than on the fact that they are significant. Second, we need to be sensitive to the paucity of variables at the patient level which we

could control, and more important, the ones we could not control such as frailty, residence, and cognitive ability all of which most likely share variance with our measured variables (i.e., gender, age, and length of stay). Lastly, we need to remain cognizant of the obvious differences that exist among fiscal intermediaries. This includes their workload, profitability, and the sufficiency of their management information systems.

In general, we found very large differences in the ability of FIs to provide timely data and, for cholecystectomies, differences in their ability to adequately screen data internally for even the simplest variables. Any analysis of this dataset should control for the effects of individual FIs. This is especially true given the volumes written on small area variation and the vast differences in Medicare reimbursement across the country. Failure to control for these effects would likely lead to severe bias.

As for the patient level variable for which we estimated coefficients, we cannot make any general conclusions. For both receiving data on time and receiving "good" data, we would generally expect the FI variables to capture most of the variance (which they do). This is because it is the FI who organized the data for delivery to the research team. It is not clear why either eligibility or timeliness of data delivery would be affected by any of the variables we measured. On the other hand, it is reasonable to believe that age is a proxy for many other variables, especially frailty, as would be length of stay. The gender results are also likely to be proxies for other unmeasured variables; this in light of the fact that women generally respond at higher rates than men, contrary to our finding.

Once entered into the sample, a large proportion of the respondents were located and agreed to participate. Losses because of no telephone number, and difficulty getting elderly patients to participate based upon a 'cold' telephone call were modest. Between the two conditions, the number of respondents who were never found due to lack of a telephone number was 10% and the number refusing to participate was 15%.

Utilizing the Peer Review Organizations to obtain copies of the medical records was also a fairly efficient and effective way to accomplish this major task. Most hospitals contacted accepted the PROs authority to obtain the record as part of their ongoing research activities. All but 1.3% of the records requested were received.

The sample was stratified to include equal numbers of inpatient open cholecystectomies, inpatient laparoscopic cholecystectomies, and outpatient laparoscopic cholecystectomies. Identifying inpatient and outpatient status was complicated by a lack of conjunction between FI data, medical record data, and HCFA data. There is a need for a clear definition of ambulatory surgery and a better understanding of the application of the definition versus billing procedures used by providers. There is some cause for concern in trying to compare the classification based on Medicare data with that obtained from records abstracts, especially for the laparoscopic cholecystectomy cases. In many instances, patients classified as outpatients spent several days in the hospital. Since this study had the advantage of being able to compare the medical record finding with the billing data, some opportunity to test the effectiveness of using the latter was afforded. In general the MEDPAR bills worked well, but there were omissions. The experience with Part B claims was less encouraging. In some cases, billings for the procedure could be found but not a bill for the surgeon. Outpatient cases might appear under outpatient claims in MEDPAR or in Part B files, in neither, or in both.

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